

that regulations on privacy of medical information should be considered. One commenter indicated that the LOINC® reporting system requires narrative reporting for some microbiology tests which is not in a data quality field format.

Response: We are pleased the commenters supported the development of measures related to the quality of clinical laboratory services. We agree that it is imperative to work with physicians, providers and the clinical laboratory community to identify quality measures that can efficiently be incorporated into the laboratory billing system. We understand the reporting of laboratory quality measures must reach compatibility with privacy rules. Furthermore, the important role of quality measures in the evolution of healthcare reporting will remain strong. While changes to information technology may be required, laboratories should be anticipating further interest to include a laboratory quality measure field in laboratory billing systems.

b. Blood Glucose Monitoring in SNFs

In the CY 2007 PFS proposed rule (71 FR 49064), we included a discussion of our longstanding policy on blood glucose monitoring in SNFs submitted for payment under the Medicare Part B clinical laboratory fee schedule. We explained that section 1862(a)(1)(A) of the Act requires

that a service be reasonable and necessary for diagnosis and treatment to be eligible for coverage by Medicare. Our regulations at §410.32(a) already require that, for any diagnostic test, including a clinical diagnostic laboratory test, to be considered reasonable and necessary, it must be both ordered by the physician and the ordering physician must use the result in the management of the beneficiary's specific medical problem. Tests not ordered by the physician who is treating the beneficiary are not reasonable and necessary.

In the context of blood glucose monitoring, we most recently explained this policy in Transmittal AB-00-108, which is available on our Web site at

<http://www.cms.gov/transmittals/downloads/ab00108.pdf>.

This interpretation of §410.32 also is the basis for our policy in section 90.1 of Chapter 7 of the Medicare Claims Processing Manual ("Skilled Nursing Facility Part B Billing," which is available on our Web site at

<http://www.cms.hhs.gov/manuals/downloads/clm104c07.pdf>.)

In addition, separate authority under section 1835(a)(2)(B) of the Act provides that, in the case of certain "medical and other health services" (including clinical diagnostic laboratory services), payment may be made for Part B services that are furnished by a provider

of services only if a physician certifies--and recertifies where those services are furnished over a period of time, with such frequency, and accompanied by such supporting material, as may be provided by regulation--that those services were medically necessary. In the CY 2007 PFS proposed rule (71 FR 49065), we proposed to use our authority under section 1835(a)(2)(B) of the Act to amend §424.24 to provide that, for each blood glucose test furnished to a resident of a SNF, the physician must certify that the test is medically necessary. We also proposed to clarify that a physician's standing order is not sufficient to order a series of blood glucose tests.

Comment: Many commenters explained that it is common medical practice in the nursing home for the physician to certify a standing order for a 1-month time period for the nurse to perform daily glucose monitoring fingerstick tests throughout the month and based on the results, the nursing staff dispense insulin, as needed by the patient. Thus, the commenters objected that the proposal will impose a burden on SNFs who perform tests under these situations.

Response: This amendment to §424.24 establishes a certification requirement that affects only services that are furnished by a provider of services for which the provider of services seeks payment under Medicare Part B.

To the extent payment is available under Medicare Part A or the services are not furnished by a provider of services (as defined under section 1861(u) of the Act), this certification requirement does not apply.

Payment for glucose monitoring is encompassed under other payment systems that are available to the nursing homes. Medicare pays as part of the bundled payment to the facility for beneficiaries in a Part A-covered stay in a hospital or in a SNF. It is when the provider requests Medicare to separately pay for a blood glucose test under the outpatient Part B clinical laboratory fee schedule that the service must meet the certification requirement under §424.24(f).

We also note that the revisions to §424.24 does not alter existing policies issued under section 1862(a)(1)(A) of the Act. As discussed above in this section, under §410.32(a), the test must be ordered by the physician who is treating the beneficiary and the physician must use the results promptly in the management of the beneficiary's specific medical condition.

Comment: Some commenters raised concerns that coverage policies are not consistently describing diabetes care categories, glucose monitoring protocols, and an

individual glucose test service. The commenters suggested more specific coverage policies would benefit providers.

Response: We understand the suggestion that refinements to coverage policies could benefit providers. The 2002 NCD for blood glucose tests specifies coverage and frequency limitations for reimbursement under the Part B. The NCD is not specific to nursing home common practices and applies to all providers submitting claims for payment under the clinical laboratory fee schedule. During the years since the release of the NCD, laboratories along with other providers who seek payment from the clinical laboratory fee schedule have had opportunity to carefully review the NCD and request further refinements and examples to enhance the NCD's interrelationship with payment under the clinical laboratory fee schedule. Interested parties can find more information on the coverage policy process on our Web site at www.cms.hhs.gov/center/coverage.asp.

With respect to the burden of this certification requirement, we believe that, by enacting section 1835(a)(2)(B) of the Act, the Congress recognized that it may be appropriate for the Secretary to impose conditions of payment for services furnished by providers of services for which providers bill separately under Medicare Part B. We recognize the value of blood glucose testing and

strongly support this testing when it is medically necessary. However, we must also ensure that blood glucose testing is medically necessary when furnished by a provider of services for which the provider bills Medicare Part B. We believe that this revision to §424.24 strikes the appropriate balance between our commitment to beneficiary access to blood glucose testing and our obligation to ensure that each test is medically necessary.

We do not believe that our amendment to §424.24 imposes a new obligation. As discussed above in this section, §410.32(a) and our program instructions already require that a laboratory test must be ordered by a physician and the ordering physician must use the result in the management of the beneficiary's specific medical problem. However, as discussed in the proposed rule, we have received inquiries regarding the application of §410.32(a) in the context of blood glucose testing provided by SNFs. In addition, we received a specific inquiry asking for clarification of section 90.1 of Chapter 7 of the Medicare Claims Processing Manual. Furthermore, we have become aware that some providers have filed claims before Administrative Law Judges challenging our policy regarding blood glucose testing in SNFs.

To the extent there has been confusion regarding our policies, our amendment to §424.24 provides a clear rule that, for payment to be made for blood glucose tests under Medicare part B to a provider of services, a physician must certify that each test is medically necessary. We also have clarified that a physician's standing order is not sufficient to order a series of blood glucose tests.

Comment: One commenter alerted that some home health providers are engaging in inappropriate physician ordering of clinical diagnostic blood glucose tests, for payment under the Part B benefit, so that the clarification to the regulation should apply not just to SNFs but also to home health agencies.

Response: We agree with the commenter that the regulation should apply to providers of services who bill to the Medicare Part B clinical laboratory fee schedule, including home health agencies. We are revising §424.24(f) to provide that the certification requirement applies to all providers of services.

Comment: One commenter disagreed with our proposal stating that it would impose an unfair burden on clinical laboratories that provide services to SNFs because the independent laboratory is not informed or responsible for the documentation requirements in the SNF.

Response: Independent clinical laboratories are not providers of services, so our amendment to §424.24 does not affect these entities. We disagree that an independent clinical laboratory that is providing services to SNF customers should not be informed or ensure the medical necessity documentation is sufficient. Independent clinical laboratories must comply with §410.32(a). Furthermore, independent clinical laboratories must be certified under the Clinical Laboratory Improvement Amendments of 1988 (CLIA) (Pub. L. 100-578). Under the standard for test requests at §493.1241, the laboratory must have a written or electronic request for patient testing from an authorized person. An independent clinical laboratory, whether it is providing services to SNF customers or other provider types, must remain informed and involved to ensure the laboratory service is rendered in accordance with the regulation and instructions applicable for receiving payment under the clinical laboratory fee schedule.

Comment: One commenter asserted that we are obligated to perform a Regulatory Impact Analysis for our proposal to clarify §424.24 requiring the physician to certify each test is medically necessary and stating that a physician's standing order is not sufficient to order blood glucose

tests for payment under the Medicare Part B clinical laboratory fee schedule. Another commenter stated our amendment to §424.24 does not comport with the Paperwork Reduction Act of 1995 to publish a notice in the **Federal Register** on collection of information.

Response: We do not believe our amendment to §424.24 requires a regulatory impact analysis or a Paperwork Reduction Act notice. We believe that §424.24(f) does not impose any new obligations, but merely codifies as a condition of payment what has long been required under §410.32(a) and our program instructions.

After careful review of public comments, we are finalizing §424.24(f) as proposed.

c. Other Lab Issues--Proposed Clinical Diagnostic Laboratory Date of Service (DOS) for Stored Specimens

In the CY 2007 PFS proposed rule (71 FR 49064), we proposed to add new §414.510 to address concerns regarding the date of service of a clinical diagnostic laboratory test that use a stored (or "archived") specimen. In the final rule of coverage and administrative policies for clinical diagnostic laboratory services (66 FR 58792) that we published in the November 23, 2001 **Federal Register**, we adopted a policy under which the date of service for clinical diagnostic laboratory services generally is the